

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04-02-2010 has been entered.

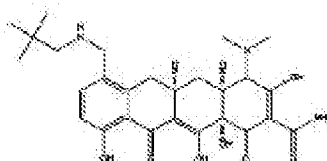
### ***Response to Amendment***

2. The amendments filed on 09/08/2009 are acknowledged. Thus currently, claims 1, 37, 39-40, 42-46, 57, 59-60, and 62-66 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Although claim 65 did not read on the elected species chosen by Applicants in the reply filed 02/20/2007 it was improperly examined with the claims encompassing the elected species, see Office Actions mailed 5-06-2009 and 12/22/2009.

5. Applicants are reminded of their election of the following species in the Reply filed 02/20/2007:



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Therefore new claim 66 will only be considered to the extent that it recites the above species.

### ***Double Patenting***

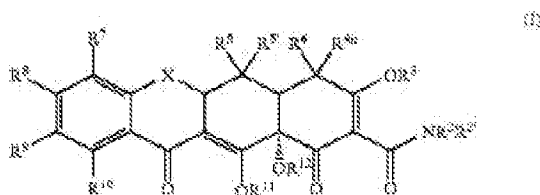
6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

7. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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8. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 37, 39-40, 42-46, 57, 59-60, and 62-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 7,935,687. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the issued claims are drawn to a method for treating a subject for a disease treatable by modulation of RNA, wherein said disease is spinal muscular atrophy, and comprising administering to said subject an effective amount of a tetracycline compound of formula I:



wherein

X is CR<sup>17</sup>R<sup>18</sup>;

R<sup>1</sup> and R<sup>2</sup> are each hydrogen;

R<sup>3</sup> and R<sup>4</sup> are each alkyl;

R<sup>5</sup>, R<sup>6</sup>, R<sup>11</sup> and R<sup>12</sup> are each hydrogen;

R<sup>7</sup> is NR<sup>13</sup>R<sup>14</sup>;

R<sup>8</sup> and R<sup>9</sup> are each hydrogen;

R<sup>10</sup> and R<sup>16</sup> are each hydrogen;

R<sup>15</sup> is scyl, amino, phenyl, pyridinyl, furanyl, pyrrolyl, tetrahydropyridinyl, quinolinyl, or aminoalkyl;

R<sup>8</sup> is hydrogen;

R<sup>9</sup> is hydrogen or phenyl; and

R<sup>10</sup> is hydroxyl;

or a pharmaceutically acceptable salt, ester or enantiomer thereof, such that said spinal muscular atrophy in said subject is treated.

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10. The instant claims differ from the issued claims to the extent that the R7 moiety of formula I in the instant claims are limited to "substituted alkenyl, substituted alkynyl, substituted phenyl, substituted or unsubstituted furanyl, or aminoalkyl." The R7 of the issued claims is limited to acyl, amino, phenyl, pyridinyl, furanyl, pyroolyl, tetrahydropyridinyl, quinolinyl, or aminoalkyl. It is clear that the definitions for R7 in the instant claims and the issued claims overlap to the extent that they are defined as aminoalkyl and furanyl. Additionally, in regards to the "substituted phenyl" limitation recited in the instant claims, it is clear that the scope of the issued claims encompassed wherein R7 is a substituted phenyl as suggested by issued claim 6 which recited wherein said phenyl or pyridinyl is of formula V.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

11. The rejection of claims 1, 37-47, 54, 57, 59-60, and 62-65 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to the issuance of US Patent 7935687 which claims common subject matter. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. EPPS -SMITH whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633